

### **REMARKS**

Claims 124-130 and 143-149 are pending in this application. Claims 124, 125, and 130 are amended to recite a "temperature about 150°C or above." Claim 128 is amended to recite a swell ratio of "about 5 or less" and a "depth from about 20  $\mu$ m to about 3 mm." The claims are amended for clarity for the reasons discussed herein. Therefore, no new matter is introduced. The Office Action is discussed below:

#### ***Rejections Withdrawn:***

On page 2 of the Office Action, the examiner has withdrawn the indefiniteness rejection of claims 124-130 and 143-149 in view of the response filed on June 20, 2007.

The examiner also has withdrawn the anticipation rejection of claims 126-129 and 147-149 and agreed that Salovey *et al.* (6,281,264, having an effective filing date of January 20, 1995) and Shalaby *et al.* (5,824,411 having an effective filing date of June 7, 1995) are not prior art to the claimed invention.

The examiner agreed that Salovey *et al.* do not teach a method wherein the irradiated UHMWPE is heated. With respect to the product claims 126-129, the examiner agreed that the Rule 131 Declaration of Merrill *et al.* shows reduction to practice of the claimed methods before Salovey *et al.*'s effective filing date of January 20, 1995.

Regarding claims 126-129 and 147-149, the examiner also agreed, in view of the response filed on June 20, 2007, that Shalaby *et al.* do not teach heating irradiated UHMWPE to a temperature above 150°C or to melting.

Applicants thank the examiner for withdrawal of the rejections.

#### ***Response to Arguments:***

On pages 2-5 of the Office Action, the examiner states that the arguments filed on June 20, 2007 are not persuasive with respect to some of the issues as discussed below:

The examiner asserts that the claims were rejected because the claim language

failed to clearly recite the method steps and/or order of steps defined in the embodiments of the invention as disclosed. The examiner opined that what is "inherently disclosed" in the specification cannot be the basis for amending an application to recite an inherent function, theory or advantage without introducing new matter. The examiner believes that embodiments of the instantly disclosed invention, specifically "MIR" or "IR-SM", comprise different orders of melting and irradiation that would be expected to produce products having significantly different properties. Applicants respectfully disagree with the examiner and refer the examiner to the dictates of the MPEP regarding the inherent function that:

"By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)." See MPEP §2163.07(a) (Rev. 6, September 2007 at 2100-192).

The examiner also asserts that in the absence of disclosure within the specification of method steps to be employed, it is not clear what steps could be considered to "inherent." Again, applicants disagree with the examiner, indicate that the claimed method steps are clearly described in various embodiments, the examiner has failed to understand the claimed processes, and attempted to limit the claims to one aspect of the invention. Applicants also refer the examiner to the MPEP § 2163 (II) for "METHODOLOGY FOR DETERMINING ADEQUACY OF WRITTEN DESCRIPTION", more specifically, MPEP §2163 (II) A (1) and (2) that dictates:

"Claim construction is an essential part of the examination process. Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description. See, e.g., *In re Morris*, 127 F.3d 1048, 1053-54, 44 USPQ2d

1023, 1027 (Fed. Cir. 1997)." (see MPEP §2163 (II) A (1) at 2100-176, Rev. 6, September 2007).

"Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention. An element may be critical where those of skill in the art would require it to determine that applicant was in possession of the invention. Compare *Rasmussen*, 650 F.2d at 1215, 211 USPQ at 327...." (see MPEP §2163 (II) A (2) at 2100-177, Rev. 6, September 2007).

Applicants also indicate that the claims should be interpreted in view of the entirety of the specification and should not be limited to any specific aspects of the invention as done by the examiner.

Regarding the previously filed Rule 131 Declaration of Merrill *et al.* (originally filed July 16, 2004 in related application no. 10/197209 in order to show completion of the instantly claimed invention prior to January 20, 1995), the examiner agreed that the data in the Declaration is considered to clearly show reduction to practice of the disclosed "MIR" process before January 20, 1995. However, in the Declaration, the examiner has failed to identify the data regarding the evidence of reduction to practice of the instantly claimed embodiment wherein irradiation is followed by melting, i.e. "IR-SM", before January 20, 1995. Applicants refer to the declaration section 11 that describes irradiation and subsequent melting aspect of the invention prior to January 20, 1995. More specifically, Exhibit 3, Experiment 2 and Exhibit 4 clearly disclose the claimed inventive method that involves irradiation and subsequent melting. Applicants indicate that the Exhibits also show additional DSC thermal analysis, which requires further melting of the irradiated UHMWPE

On pages 4 and 5 of the Office Action, the examiner states that the effective filing date for the claims, reciting a process for preparing a medical implant comprising irradiating an UHMWPE article followed by thermal treatment by remelting and cooling, fabricating an implant and sterilizing, is October 2, 1996, thus Shen '900 patent is a prior art to the instant invention. According to the examiner, the application 08/600,744, filed February 13, 1996, does not disclose irradiation followed by melting

the irradiated UHMWPE.

Applicants disagree with the examiner and submit that the effective filing date for the instant application is February 13, 1996, which predates July 9, 1996, the claimed priority date for the Shen '900 patent.

Applicants refer to the specification, filed February 13, 1996, that has support for a process for preparing a medical implant comprising irradiating an UHMWPE article followed by thermal treatment by remelting and cooling. Applicants also refer to Example 6 on pages 44-46 (of the 08/600,744 specification), for example, that the thermal treatment was continued through the irradiation process of cross-linking, including between two or after each dose of irradiation. Also, for example, for a total dose of 5-20 Mrads at the dose rate of 2.5 Mrad per pass, it takes at least two passes of irradiation while the polyethylene is thermally treated in between two or after each dose of irradiation (see for example, Example 9 at pages 48-49). Applicants indicate that this is further evidenced by the fact that the van de Graaff generator used at the time generated a dose rate of 2.5 Mrad per pass (see specification, for example, page 33, 41, and 45). Therefore, the UHMWPE article according to the claimed invention is prepared by irradiating the UHMWPE article and subjecting the crosslinked UHMWPE article to remelting.

Applicants further refer the examiner to the US 5,879,400 (which issued from the application serial no. 08/600,744) column 13, lines 14-62 and pages 27-29 of the originally filed specification for the application serial no. 08/600,744.

Applicants refer to the previously filed declaration pursuant to 37 C.F.R. § 1.131 (filed on May 26, 2004) that contains data showing the completion of both the MIR and CISM embodiments of the invention prior to January 20, 1995. Applicants indicate that the declaration evidenced that the completion of the claimed method steps of subjecting the crosslinked polyethylene to remelting was prior to January 20, 1995 (see Exhibits 1, 3, and 4). Accordingly, the Shen '900 patent with the claimed priority date of July 9, 1996 is not a prior art against the claimed invention.

On page 5 of the Office Action, the examiner asserts that Hyon *et al.* (6,168,626, having an effective filing date of May 6, 1996) antedates the claimed invention. According to the examiner, Hyon *et al.* disclose UHMWPE molded articles for artificial joints prepared by irradiating an UHMWPE molded article and subsequently heating to the compression-deformation temperature, a temperature not less than the melting point. Applicants disagree with the examiner and refer to above discussion and arguments that the claimed method comprising irradiating UHMWPE and subsequently melting of the irradiated UHMWPE was reduced to practice prior to January 20, 1995. Accordingly, Hyon's '626 patent with the claimed priority date of May 6, 1996 is not a prior art against the claimed invention.

In addition, applicants point out that Hyon's material is deformed under compression after it is irradiated and cooled down under deformation, therefore resulting in an anisotropic material due to the preferred molecular and crystalline orientation induced by the deformation. Instantly claimed processes or the implants cannot have any appreciable level of anisotropy in the material as they are not subject to deformation. Further, applicants point out that Hyon process is limited by a maximum irradiation dose of 5 Mrad, which is not enough to yield medical implants having balance of wear properties and oxidation resistance. Therefore, Hyon does not anticipate the claimed invention.

***Claim Interpretation and Effective Filing Date:***

On pages 5-6 of the Office Action, the examiner interprets that claims 124-130 and 143-149 recite the irradiation and subsequent melting method ("IR-SM") was first disclosed in SN 08/726,313, filed October 2, 1996. Thus, opined that claims 124-130 and 143-149, wherein the irradiation step precedes the melting step have an effective filing date of October 2, 1996, and February 13, 1996 is the filing date of the priority application SN 08/600,744. Therefore, the examiner considers that the earliest effective filing date of the instant claims wherein the method steps comprise irradiation followed by melting the irradiated UHMWPE is October 2, 1996 filing date of SN 08/726,313. Applicants disagree with the examiner and submit as discussed above and as evidenced by the declaration and the Exhibits that the instantly claimed

embodiment wherein irradiation is followed by melting, i.e. "IR-SM", was reduced to practice prior to January 20, 1995.

On page 6 of the Office Action, the examiner asserts that claims 128-129 are not supported by the disclosure of SN 08/600,744 and does not disclose the swell ratio or degree of oxidation of the crosslinked UHMWPE. Thus, opines that claims 128-129 are not entitled to the February 13, 1996. Applicants disagree with the examiner and refer to the original specification, for example, Example 4, Tables 2 and 6; and Example 11, Tables 8 and 11 for support.

***New Rejections under 35 USC § 112, second paragraph:***

On pages 6-7 of the Office Action, the examiner rejects claims 124-125, 128, and 130 under 35 U.S.C. 112, second paragraph, allegedly as being indefinite for recitation of the phrase "temperature above about 150°C" in claims 124, 125, and 130, and the phrases "less than about 5" and "between about 20 µm to about 3 mm" in claim 128.

According to the examiner, claims 124, 125, and 130 should recite a temperature "above 150°C" or a temperature "about 150°C".

Applicants disagree with the examiner and indicate that the claims are copied from the U.S. Patent No. 6,017,975 (Saum *et al.*, the '975 patent) to provoke an interference and the phrase "temperature above about 150°C" also is recited in the claims of the '975 patent (see for example, claims 1, 15 and 35). Applicants indicate that the phrase is clearly understandable to one skilled in the art that the phrase "temperature above about 150°C" refers to a temperature of "about 150°C or above." For clarity, without acquiescing in the rejection, applicants amend the claims to recite the phrase as a "temperature about 150°C or above."

With respect to claim 128, the examiner opines that the claim should recite "less than 5" or "about 5", or "depth between..." or "depth from about ...". Again, applicants disagree with the examiner and submit as above that the phrase "less than about 5" also is copied from the '975 patent (see for example, claim 32). Applicants indicate that the phrase is clearly understandable to one skilled in the art that the phrase "less than

about 5" refers to "about 5 or less." Again, for clarity, without acquiescing in the rejection, applicants amend the claim to recite the phrase as "about 5 or less."

Regarding the phrase "between about 20  $\mu$ m to about 3 mm" in claim 128, applicants amend the claim for clarity to recite a "depth from about 20  $\mu$ m to about 3 mm" as suggested by the examiner.

In view of the above, applicants request withdrawal of the indefiniteness rejection.

***Claim Rejections - 35 U.S.C. § 102:***

On page 7 of the office action, the examiner has maintained the rejection of claims 124-130 and 143-149 allegedly as being anticipated by Shen *et al.* (6,228,900, which claims priority to a provisional application serial no. 60/017,852, filed July 9, 1996).

The examiner reiterates that the effective filing date for a process comprising irradiation followed by melting the irradiated UHMWPE is October 2, 1996 (which is the filing date of SN 08/726,313) and Shen *et al.* disclose a process for preparing a medical implant comprising irradiating an UHMWPE article followed by thermal treatment by remelting and cooling, fabricating an implant and sterilizing.

Applicants disagree with the examiner and refer to above argument and indicate that the instant application claims priority to U.S. Serial No. 08/726,313 (filed October 2, 1996), which was filed as a continuation-in-part of U. S. Serial No. 08/600,744 (filed February 13, 1996).

Applicants also indicate that a patent applicant need not show completion of every embodiment of an invention in a Rule 1.131 declaration\*, the declaration provided by the applicants contains data showing the completion of both the MIR and CISM embodiments of the invention prior to January 20, 1995. Therefore, the Shen '900

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\* As explained by the Court of Customs and Patent Appeals in *In re Fong*, 288 F.2d 932, 936 (CCPA 1961), a 131 declaration is sufficient if it shows a species of an invention.

patent does not qualify as a prior art under 35 USC § 102(e) because applicant's initial filing antedates Shen's filing dates.

On pages 7-8 of the office action, the examiner also has maintained the rejection of claims 126-129 and 143-149 allegedly as being anticipated by Hyon *et al.* (6,168,626, claiming a priority date of May 6, 1996).

The examiner reiterates that Hyon *et al.* disclose UHMWPE molded articles for artificial joints prepared by irradiating an UHMWPE molded article and subsequently heating to the compression-deformation temperature, a temperature not less than the melting point (refers to column 3, line 16, to column 5, line 13). With respect to claim 126 and 127, according to the examiner, the products disclosed by Hyon *et al.* would be expected to have the same properties as the instantly claimed products.

Applicants disagree with the examiner, traverse the rejection, and refer to the arguments as above that the initial filing date antedates Hyon's claimed filing date. Therefore, Hyon *et al.* is not a prior art to instant application, thus the rejection is improper.

In addition, as discussed above, applicants point out that Hyon's material is deformed under compression after it is irradiated and cooled down under deformation, therefore resulting in an anisotropic material due to the preferred molecular and crystalline orientation induced by the deformation. Instantly claimed processes or the implants cannot have any appreciable level of anisotropy in the material as they are not subject to deformation. Applicants reiterate that Hyon process is limited by a maximum irradiation dose of 5 Mrad, which is not enough to yield medical implants having balance of wear properties and oxidation resistance. Therefore, Hyon does not anticipate the claimed invention.

#### ***Double Patenting Rejections:***

On pages 8-10 of the office action, the examiner has maintained the provisional obviousness-type double patenting rejection of the claims and alleged as being directed to the same invention as the claims of co-pending application serial nos. 10/948,440, 10/197,209, 10/696,362, 10/901,089, and 10/197,263.

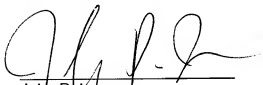


Applicants reiterate that because applicants have not received a notice of allowance for the 10/948,440, 10/197,209, 10/696,362, 10/901,089, or 10/197,263, the merits of this provisional rejection need not be discussed with the examiner at this time. See MPEP § 822.01.

**REQUEST**

Applicants submit that claims 124-130 and 143-149 are in condition for allowance, and respectfully request favorable consideration to that effect so that an interference can be declared with applicants as the senior party by virtue of the priority afforded by the priority applications. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,

  
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John P. Isacson  
Reg. No. 33,715

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Date

PROSKAUER ROSE LLP  
1001 Pennsylvania Avenue, N.W.  
Suite 400 South  
Washington, D.C. 20004  
Phone: 202-416-6800  
Fax: 202-416-6899  
Customer No. 61263